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10/812,912	03/31/2004	Francis Blanche	08888.0517-01	5703

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EXAMINER
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WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/812,912

Applicant(s)

BLANCHE ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-14 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) 20,21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 13,14 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date 6/27/06
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### **Non-Final Rejection**

Claims 10-14 and 17-22 are pending.

Applicant's traversal, the amendment to the specification, the amendment to claim 10, and the addition of claim 22 filed on 3/10/06 is acknowledged and considered by the examiner.

The Declarations under 1.131 filed on 3/10/06 list the incorrect application number. See interview summary.

### ***Election/Restrictions***

Since claim 15 was cancelled and the amendment to claim 10 to recite "Tris/HCl buffer solution" the restriction for buffer solution is moot.

Sugar and Alcohol in claim 18 and claims 20 and 21 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/10/06.

### ***Claim Objections***

Claims 13-14 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Tryggvason et al. (US 5,871,464). Tryggvason teaches an adenoviral preparations stored in 10 mM Tris-HCl and 10% glycerol at -70C (column 5).

Applicant's arguments, see pages 5-6, filed 3/10/06, with respect to the rejection(s) of claim(s) 10-12 and 15-19 under 102(e) have been fully considered and are persuasive. The rejection of claims 10-12 and 15-19 has been withdrawn because of the Declaration by the inventors.

The Declaration filed on 3/10/06 under 37 CFR 1.131 is sufficient to overcome the 102(e) reference. The Declaration under 1.131 shows the reduction to practice to the claimed invention occurred prior to November 16, 1998, priority for Wu published patent application. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of Tryggvason (US 5,871,464).

Claims 10 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Tryggvason et al. (US 5,871,464). Tryggvason teaches an adenoviral preparations stored in 10 mM Tris-HCl and 10% glycerol at -70C (column 5).

Applicant's arguments, see pages 5-6, filed 3/10/06, with respect to the rejection(s) of claim(s) 10-12 and 15-19 under 102(e) have been fully considered and are persuasive. The rejection of claims 10-12 and 15-19 has been withdrawn because of the Declaration by the inventors.

The Declaration filed on 3/10/06 under 37 CFR 1.131 is sufficient to overcome the 102(e) reference. The Declaration under 1.131 shows the reduction to practice to the claimed invention occurred prior to November 16, 1998, priority for Wu published patent application. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of Tryggvason (US 5,871,464).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 12, 17, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tryggvason et al. (US 5,871,464) taken with Sene (WO 98/02522, see english equivalent US 6,451,256, cited on a PTO-892). Tryggvason teaches an adenoviral preparations stored in 10 mM Tris-HCl and 10% glycerol at -70C (column 5). However, Tryggvason does not specifically teach the preparation further comprising a polymer, wherein the polymer is polyethylene glycol.

However, at the time the invention was made, Sene teaches that a recombinant virus suspension comprising an aqueous sucrose solution for preserving recombinant virus particles in frozen or liquid form (abstract). Sene teaches that preservation of the viruses can be improved by using at least one stabilizer TWEEN 80 (polysorbate) or TRITON X-100 (polyethylene glycol) (column 3). Sene teaches an adenovirus preparation at 4°C (page 7).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Tryggvason taken with Sene, namely to

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produce composition comprising adenovirus stored in 10 mM Tris-HCl, 10% glycerol, and an adjuvant, wherein the adjuvant is a polymer (e.g., TWEEN 80 and TRITON X-100). One of ordinary skill in the art would have been motivated to combine the teaching to improve preservation of the viruses.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Tryggvason taken with Sene, namely to produce composition comprising adenovirus stored in 10 mM Tris-HCl, 10% glycerol, wherein said composition is at a temperature ranging from 4°C to 20°C. One of ordinary skill in the art would have been motivated to combine the teaching for short-term storage of the adenovirus.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments, see pages 5-6, filed 3/10/06, with respect to 103(a) have been fully considered and are persuasive. The rejection of claims 13 and 14 has been withdrawn because of the Declaration by the inventors (See reasons under the prior art rejection under 102). However, upon further consideration, a new ground(s) of rejection is made in view of Tryggvason (US 5,871,464) taken with Sene.

### ***Response to Arguments***

Applicant's arguments, see page 7, filed 3/10/06, with respect to odp rejection have been fully considered and are persuasive. The rejection of claims 10-12 and 15-19 has been withdrawn because of the terminal disclaimer over 6,743,008.

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Applicant's arguments, see page 7, filed 3/10/06, with respect to statutory double patenting rejection have been fully considered and are persuasive. The rejection of claims 13 and 14 has been withdrawn because of the amendment to claim 10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, SPE – Art Unit 1635, can be reached at (571) 272-4517.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman

**BRIAN WHITEMAN**  
**PATENT EXAMINER**  
*B. Wh*